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Proposed Registration Decision PRD2013-16

Sodium Lauryl Sulfate

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Overview

Proposed Registration Decision for Sodium Lauryl Sulfate

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Stepanol DX (AS165) N and MTDX-CR, containing the technical grade active ingredient sodium lauryl sulfate, to kill German cockroach adults and nymphs in and around buildings.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of Stepanol DX (AS165) N and MTDX-CR.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on sodium lauryl sulfate, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on sodium lauryl sulfate, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation section of this consultation document.

What Is Sodium Lauryl Sulfate?

Sodium lauryl sulfate, the technical grade active ingredient in the technical product Stepanol DX (AS165) N, is a sodium salt of a long hydrocarbon chain linked to sulfate. Formulated as the end-use product MTDX-CR and used in and around buildings, it kills German cockroach nymphs and adults on contact.

Health Considerations

Can Approved Uses of Sodium Lauryl Sulfate Affect Human Health?

MTDX-CR containing sodium lauryl sulfate is unlikely to affect human health when used according to label directions.

Exposure to sodium lauryl sulfate may occur when applying the end-use product, MTDX-CR, or when people enter a freshly treated site. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient sodium lauryl sulfate is expected to be slightly acutely toxic by the oral route, moderately acutely toxic by the dermal route, severely irritating to the skin, eyes, and respiratory tract, and is not a skin sensitizer.

Exposure to humans from the commercial use of MTDX-CR is not expected to be of concern due to the precautionary statements present on the end-use product label that are aimed at mitigating exposure.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Residues in Food and Water

Dietary risks from sodium lauryl sulfate on food and water are not of concern.

MTDX-CR is not for direct application to food. Also, the end-use product label has precautionary statements not to contaminate food, feed, and water with the end-use product; therefore, dietary exposure to sodium lauryl sulfate from the proposed end-use product use is anticipated to be negligible.

No risk due to exposure from drinking water is anticipated as sodium lauryl sulfate is unlikely to persist in the environment to the extent that it could be consumed in drinking water.

Risks From Handling MTDX-CR

Risks are not of concern when MTDX-CR containing sodium lauryl sulfate is used according to label directions, which include precautionary statements.

MTDX-CR is to be applied by commercial applicators inside and outside buildings.

Occupational exposure is of concern during handling, loading and mixing of MTDX-CR and clean-up activities when workers are exposed to the concentrated form (98% w/w); however, risks from exposure are not anticipated when workers follow label directions which include exposure mitigation measures, such as personal protective equipment (PPE), cautionary, hygiene, and restricted-entry statements on the end-use product label.

Environmental Considerations

What Happens When Sodium Lauryl Sulfate Is Introduced Into the Environment?

The insecticide, MTDX-CR, is proposed to be applied in and around buildings to kill German cockroaches (*Blatta germanica*). As the application method is a handheld sprayer pump, and the product is applied directly to the target pest, the exposure to non-target organisms is expected to be negligible. The risk to the environment is not expected to be a concern.

Value Considerations

What Is the Value of MTDX-CR?

MTDX-CR is a non-conventional product which kills German cockroach nymphs and adults on contact, in and around buildings. German cockroaches can be pests in these areas. MTDX-CR is applied directly on German cockroaches. The active ingredient, sodium lauryl sulfate, is a new mode of action for use against cockroaches.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of MTDX-CR to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The signal words "WARNING – POISON," "DANGER – SKIN IRRITANT," and "DANGER – EYE IRRITANT" are required on the principal display panels of the labels of Stepanol DX (AS165) N and MTDX-CR.

Standard hazard and precautionary statements are also required on both the labels to inform workers of the irritation potential of the active ingredient and to caution that it is harmful when swallowed, inhaled or absorbed through the skin.

Based on the hazard profile (for example, likelihood to irritate the respiratory tract and oral mucosa), standard PPE are required for mixers and loaders, for example, long clothing, shoes and socks, waterproof gloves, protective eyewear, and respirator.

A precautionary statement on the end-use product label indicating that the handling, loading/mixing of the end-use product, as well as the clean-up and maintenance activities must be performed in a well-ventilated area is required.

Label statements advising individuals not to allow contact of the products with skin, eyes or clothing and to avoid breathing dust or spray mist are required.

To protect bystanders, label statements are required to instruct that the product must not be applied in a way that it will contact workers or other persons, either directly or through drift, and indoor application of the end-use product in commercial facilities is restricted to vacant areas only.

To protect from postapplication exposure, a label statement is required to restrict entry/re-entry into treated areas until the spray is dried and the areas are thoroughly ventilated.

The end-use product label instructs that workers not contaminate food or feed, and cover food contact surfaces and equipment during treatment or, alternatively clean them thoroughly before reuse.

Next Steps

Before making a final registration decision on sodium lauryl sulfate, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on sodium lauryl sulfate (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Sodium lauryl sulfate

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Sodium lauryl sulfate
Function	Insecticide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Sodium dodecyl sulfate
2. Chemical Abstracts Service (CAS)	Sulfuric acid monododecyl ester sodium salt
CAS number	151-21-3
Molecular formula	$C_{12}H_{25}SO_4Na$
Molecular weight	288.38
Structural formula	
Purity of the active ingredient	98.13% Sodium alkyl (65–75% C12, 21–30% C14, 4–8% C16) sulfate

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product - Stepanol DX (AS165) N

Property	Result
Colour and physical state	White solid
Odour	Odourless
Melting range	205.5°C
Boiling point or range	Not applicable
Density	0.556–0.594 g/mL
Vapour pressure at 25°C	3.24×10^{-4} Pa
Henry's law constant at 20°C	2.758×10^{-7} Pa m³/mol
Ultraviolet (UV)-visible spectrum	No absorbance expected at $\lambda > 300$ nm
Solubility in water	> 338.75 g/L

Property	Result
Solubility in organic solvents at 20°C (g/100 mL)	Solvent / Solubility Methanol / 45.28 Hexane / 0.14
n-Octanol-water partition coefficient (K_{ow})	Log K_{ow} = 1.6
Dissociation constant (pK_a)	pKa of dodecyl hydrogen sulfate = -3.29 (acidic at 25°C)
Stability (temperature, metal)	Will hydrolyze at room temperature under slightly acidic conditions (below pH 5). Stable at 50°C for 28 days.

End-Use Product - MTDX-CR

Property	Result
Colour	White
Odour	Odourless
Physical state	Solid
Formulation type	Solid
Guarantee	Sodium alkyl (65–75% C12, 21–30% C14, 4–8% C16) sulfate
Container material and description	Plastic canister, 907 g (2 lbs)
Density	0.556–0.594 g/mL
pH of 1% dispersion in water	9.64
Oxidizing or reducing action	Incompatible with oxidizing agents.
Storage stability	Stable for 1 year at ambient temperatures in high-density polyethylene (HDPE) containers.
Corrosion characteristics	The product is non-corrosive to the packaging materials.
Explodability	The product is not potentially explosive.

1.3 Directions for Use

Mix 10.0 grams of product into 1 litre of warm water. This product kills on contact with no residual activity. German cockroaches must be contacted directly with the liquid and become saturated. Thoroughly spray areas where German cockroaches are usually found, such as cracks and crevices, niches, dark corners, drains and other harborage sites.

1.4 Mode of Action

Sodium lauryl sulfate has a physical mode of action and kills by suffocation and desiccation.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Stepanol DX (AS165) N have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

Residue analysis for non-conventional products are not required, therefore, no methods have been reviewed.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The applicant submitted toxicology information from databases and published sources, a material safety data sheet, and a list of citations on sodium lauryl sulfate to address the data requirements for the technical grade active ingredient. Since the end-use product is a repack of the technical grade active ingredient, the toxicological profiles of the technical grade active ingredient and the end-use product are the same.

The PMRA conducted a detailed review of the submitted information and publicly available toxicological information for sodium lauryl sulfate. Sodium lauryl sulfate is slightly acutely toxic by the oral route in rats and moderately acutely toxic by the dermal route in rabbits (Appendix I, Table 1). It is severely irritating to the skin and eye in rabbits, and is not a skin sensitizer in Guinea pigs and mice. The degree of irritation caused by sodium lauryl sulfate solution depends on the volume and concentration of the tested solution. Due to the irritation potential of sodium lauryl sulfate, it is likely to irritate the respiratory tract. In humans, it has been reported to irritate the respiratory tract and oral mucosa, especially in individuals predisposed to recurrent mouth ulcers.

Negative results were reported in an Ames test (bacterial mutation), a gene mutation and sister chromatid exchange test in mammalian cells, and in an in vivo micronucleus assay in mice indicating that sodium lauryl sulfate is not genotoxic.

There is limited information available on the short-term and chronic toxicity of sodium lauryl sulfate, and it is available in summary form.

Dermal exposure (intact and abraded skin) of rabbits (3 controls, 6/treatment group) to a 20% solution of sodium lauryl sulfate at 0, 6, 60 and 150 mg/kg bw/day for 90 days showed no treatment-related effects on body weight, blood chemistry, or blood cell counts. A detailed examination of tissues showed no alteration at any tested dose. At the highest dose, 2/6 rabbits died, one with diarrhea and one with pulmonary congestion, but these mortalities were reported to be not from the treatment.

In a two-year chronic oral feeding study in rats, sodium lauryl sulfate produced no abnormalities at 0.25%, 0.5%, and 1.0% in the diet. Weight gains were normal during the study, and tissues collected at necropsy were free of gross and microscopic abnormalities. The study authors concluded that sodium lauryl sulfate was not toxic at concentrations up to 1.0 % (10, 000 ppm) in the diet.

Sodium lauryl sulfate was not carcinogenic in beagle dogs in a one-year chronic oral study at concentrations up to 2% in the diet. However, the study was of limited utility as results could not be verified by the PMRA.

Sodium lauryl sulfate when administered to male mice at 0.1% (approximately 120 mg/kg/day) for 42 days and 1% (approximately 1200 mg/kg/day) for 14 days did not show impairment of epididymal sperm to indicate effects on fertility.

Information on the developmental toxicity of sodium lauryl sulfate is limited. In developmental toxicity studies in the mouse and rabbit, a maximum dose of 600 mg/kg bw/day caused total resorption of fetuses, increased litter loss and/or abortion in the presence of severe maternal toxicity. No developmental toxicity was seen at the next highest dose of 300 mg/kg bw/day although maternal toxicity of a slight to moderate nature was noticed. Because the developmental effects observed were a secondary non-specific consequence of severe maternal toxicity, sodium lauryl sulfate is not considered to be a developmental toxicant.

There was no evidence in the available scientific literature to indicate that sodium lauryl sulfate is a neurotoxicant.

3.1.1 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website.

As sodium lauryl sulfate is not registered for pesticidal use in Canada, there are no incidents reported. As of 21 March 2013, there are also no incident reports in the California Pesticide database and no incidents in the United States Environmental Protection Agency database.

A search of the available literature and toxicology databases indicate adverse effects reported in human and animals from the irritation potential of sodium lauryl sulfate. The PMRA concluded that the information supported the current toxicity database; however, it did not impact the risk assessment.

3.2 Food Residue Exposure Assessment

Since there is no direct application of the end-use product to food and the label has precautionary statements not to contaminate food or feed, dietary exposure to sodium lauryl sulfate from the proposed end-use product use is anticipated to be negligible. The label also directs that food

contact surfaces and equipment must be covered during treatment or cleaned with an effective detergent and rinsed with potable water before reuse.

3.2.1 Drinking Water

Dietary exposure to sodium lauryl sulfate from drinking water is not likely to occur because the proposed application of the end-use product is for use in commercial food-handling and processing areas. Due to its biodegradability, sodium lauryl sulfate is unlikely to persist in the environment to the extent that it could be consumed in drinking water.

3.2.2 Maximum Residue Limits (MRLs)

A maximum residue limit (MRL) for sodium lauryl sulfate is not necessary because MTDX-CR will not be applied directly to food; therefore, dietary exposure to sodium lauryl sulfate from the proposed use of the end-use product is considered negligible.

There are no CODEX maximum residue levels (MRLs) established for sodium lauryl sulfate and the United States Environmental Protection Agency has exempted sodium lauryl sulfate from the requirement of a tolerance for residues when used as a component of food contact sanitizing solutions applied to all food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum level of 350 ppm in the end use concentration.

3.3 Occupational Exposure and Risk Assessment

3.3.1 Use Description

MTDX-CR is proposed for commercial application to control German cockroaches, inside and outside of commercial food-handling and processing areas/buildings, such as in bakeries, beverage plants, bottling facilities, breweries, cafeterias, food processing plants, candy plants, canneries, cereal processing and manufacturing plants, frozen food plants, meat processing and packaging plants, meat and vegetable canneries, hospital kitchens, hotel and motels, industrial building kitchens, office building kitchens, restaurants, food retail buildings, school kitchens, and supermarkets. The application sites identified on the label include cracks and crevices, niches, dark corners, drains, and other harbourage sites. The proposed use site categories are Stored Food and Feed (12) and Structural (20). There is no direct application to food.

MTDX-CR is to be diluted with water in a compressed air sprayer and applied as a surface, crack, crevice, and spot spray at a dilution of 10 g product/L of warm water. Application rate or frequency of application is not proposed. The label instructs applicators to not contaminate food, feed, or any body of water.

3.3.2 Occupational exposure and risk assessment

Mixer, Loader, and Applicator Exposure and Risk Assessment

The proposed use of MTDX-CR may result in exposure to the mixer, loader, and applicator, as well as those responsible for clean-up and maintenance activities. Workers will be primarily exposed to the end-use product by both inhalation and dermal routes.

Review of toxicological information on sodium lauryl sulfate indicates that it is slightly acutely toxic by the oral route, moderately acutely toxic by the dermal route, and severely irritating to eyes and skin in animals. The major human health hazards reported in scientific literature from exposure to sodium lauryl sulfate is irritation of the skin, eyes, and the respiratory tract, and the severity of the effect is concentration-dependent.

Reported effects from exposure to sodium lauryl sulfate include irritation in the upper respiratory tract including cough, labored breathing, headaches, dry throat, or nasal congestion associated with inhalation exposure; redness and pain resulting from dermal exposure, and dermatitis from repeated or prolonged occupational dermal exposure; and corneal damage from eye exposure.

Occupational exposure from the proposed use is of concern during handling, loading and mixing of the end-use product and clean-up activities when workers are exposed to the concentrated form (98%w/w), resulting in severe irritation to skin, eyes, and respiratory tract.

Inhalation exposure to applicators from spray mist and dermal exposure during application and from contact to freshly treated wet surfaces are also likely. Since the spray solution is a 1% w/w dilution of the concentrate in water, it is likely to be slightly irritating to skin, eyes and respiratory tract. Due to the diluted nature of spray and targeted application, to cracks and crevices, niches, dark corners, drains, and other harbourage sites, occupational exposure resulting from product application is not expected to raise a toxicological concern.

The end-use product label has a number of exposure reduction statements (for example, the wearing of personal protective equipment, including long clothing, as well as hygiene and precautionary statements) to protect workers against any unnecessary risk from exposure. The persons handling the concentrated end-use product, mixing/loading, and those involved in clean-up and maintenance activities must wear: a long-sleeved shirt and long pants, shoes, socks, waterproof gloves, protective eyewear, and a NIOSH-approved particulate filter respirator adapted to the airborne concentration of the substance. The persons handling diluted 1% solution must wear: a long-sleeved shirt and long pants, shoes, socks, water-proof gloves, and protective eyewear. Also, the label instructs individuals to avoid contact of the product with skin, eyes or clothing and avoid breathing dust or spray mist.

3.3.3 Bystander Exposure

As the commercial application involves only authorized personnel, bystander exposure is expected to be negligible when the end-use product is used according to the label directions. The product must not be applied in a way that it will contact workers or other persons, either directly

or through drift, and indoor application of the product in commercial facilities be restricted to vacant areas only.

3.3.4 Postapplication Exposure

Postapplication exposure is possible when people enter the treated areas soon after the application. The primary route of exposure for re-entry workers/individuals is dermal from contact with freshly treated surfaces and inhalation exposure to particulates in the air. To mitigate the potential for postapplication exposure, a precautionary label statement is required to restrict entry/re-entry until the spray is dried and that the treated areas be thoroughly ventilated.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

The active ingredient, sodium lauryl sulfate (SLS), is widely used in cosmetics and other household and industrial products. Hydrolysis of this substance is not expected to occur due to the lack of hydrolysable functional groups. The relatively low vapour pressure (3.24×10^{-4} Pa @ 25°C) and Henry's law constant (2.758×10^{-7} Pa m³/mol) indicates that it is not expected to volatilize from water or moist soil surfaces. The log K_{ow} (1.6) indicates that SLS is unlikely to bioaccumulate. Although sodium lauryl sulfate may have a tendency to adsorb quickly to soil particles, it is very soluble in water and biotransforms rapidly in aerobic soil (74% to 100% degradation within 30 days). The active ingredient SLS is, therefore, not expected to persist in the environment.

Environmental Risk Characterization

The product MTDX-CR, containing the active ingredient SLS, is proposed to be applied in and around buildings to kill accessible and exposed stages of German cockroaches (*Blatta germanica*). As the application method is a handheld sprayer pump where the diluted product is applied directly to the target pest, the exposure to non-target organisms is expected to be negligible. As such, a characterization of the risk to non-target organisms in the environment will not be conducted at this time. If the use of products containing SLS was expanded to included larger scale uses, an environmental risk characterization could be conducted.

5.0 Value

5.1 Effectiveness Against Pests

The submitted efficacy trial demonstrated that MTDX-CR kills German cockroach adults on contact. The pest must be saturated with a solution of 10 g MTDX-CR/L of water.

5.1.1 Acceptable Efficacy Claims

The submitted efficacy data supported a claim of killing German cockroach nymphs and adults on contact in and around buildings at a concentration of 10 g MTDX-CR/L of water.

5.2 Non-safety Adverse Effects to Surfaces

Sodium lauryl sulfate is commonly found in detergents used on hard and soft surfaces in structures. Therefore, it is not expected that MTDX-CR would cause stains or adversely affect surfaces when applied as directed. To mitigate concerns regarding potential adverse effects a statement advising the user to test an inconspicuous spot first is included on the label.

5.3 Sustainability

5.3.1 Survey of Alternatives

The alternative active ingredients registered to control German cockroaches in and around buildings include carbamate, organophosphate and synthetic pyrethroid insecticides, abamectin and imidacloprid. See Appendix I, Table 2 for a list of alternative active ingredients.

5.3.2 Compatibility with Current Management Practices Including Integrated Pest Management

MTDX-CR is expected to be compatible with current management practices for use against German cockroaches inside and outside buildings.

5.3.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

The mode of action of sodium lauryl sulfate is suffocation caused by blocking breathing holes and desiccation caused by dissolving the waxy coating of insects. These are physical modes of action; therefore, development of resistance to this active ingredient is unlikely.

5.3.4 Contribution to Risk Reduction and Sustainability

MTDX-CR is compatible with integrated pest management programs. The product could be used if alternatives to conventional pesticides are needed.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet

all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, Stepanol DX (AS165) N was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

Stepanol DX (AS165) N (sodium lauryl sulfate) does not meet Track 1 criteria, and is not considered a Track 1 substance.

Sodium lauryl sulfate does not meet the Track 1 criteria and will not form any transformation products which meet the Track 1 criteria. Sodium lauryl sulfate is not expected to be persistent or bioaccumulative in the environment.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02[8], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

Stepanol DX (AS165) N technical and the end-use product MTDX-CR do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02[9].

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5 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

9 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

7.0 Summary

7.1 Human Health and Safety

The applicant submitted toxicology information collected from databases and published sources. Sodium lauryl sulfate is slightly acutely toxic by the oral route in rats, moderately acutely toxic by the dermal route in rabbits, severely irritating to the skin and eyes in rabbits, and is not a skin sensitizer in Guinea pigs and mice. Sodium lauryl sulfate is known to irritate the respiratory tract. There is no evidence to indicate that sodium lauryl sulfate is carcinogenic, genotoxic, neurotoxic or that it is a developmental or reproductive toxicant.

Occupational exposure and the potential for severe irritation to skin, eyes, and respiratory tract from the proposed use is of concern during handling, loading and mixing of the end-use product and clean-up activities when workers are exposed to the concentrated form (98%w/w); however, risks from occupational exposures are not anticipated when workers follow label directions.

An MRL for sodium lauryl sulfate is not necessary as the end-use product will not be applied directly to food, and therefore dietary exposure to sodium lauryl sulfate from the proposed use of the end-use product is considered negligible.

7.2 Environmental Risk

The potential exposure of sodium lauryl sulfate to non-target aquatic and terrestrial organisms, as a result of the use of MTDX-CR as a commercial insecticidal spray to kill German coakroaches in and around buildings, is negligible. The risk to the environment is not expected to be a concern.

The risk to non-target organisms is considered to be negligible when MTDX-CR is used according to the label.

7.3 Value

MTDX-CR kills German cockroach nymphs and adults on contact in and around buildings. The product could be used if alternatives to conventional pesticides are needed. The active ingredient, sodium lauryl sulfate, is a new mode of action for use against German cockroaches.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Stepanol DX (AS165) N and MTDX-CR, containing the technical grade active ingredient sodium lauryl sulfate, to kill German cockroach adults and nymphs in various structures.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

λ	wavelength
bw	body weight
CAS	Chemical Abstracts Service
DACO	data code
EPA	United States Environmental Protection Agency
g	gram
HDPE	high-density polyethylene
IUCLID	International uniform chemical information database
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	*n*–octanol-water partition coefficient
L	litre
lbs	pounds
LD_{50}	lethal dose 50%
m	metre
mg	milligram
mL	millilitre
mol	mole
MRL	maximum residue limit
NIOSH	National Institute for Occupational Safety and Health
nm	nanometres
Pa	pascals
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
SLS	sodium lauryl sulfate
TSMP	Toxic Substances Management Policy
UV	ultraviolet
w/v	weight per volume dilution
w/w	weight per weight dilution

Appendix I Tables and Figures

Table 1 Toxicology profile of Sodium Lauryl Sulfate

STUDY	SPECIES/STRAIN AND DOSES	RESULT	SIGNIFICANT EFFECTS/ COMMENTS	REFERENCES (PMRA number)
Oral Toxicity	Rats 5 (per sex) 85% active material administered by intubation as a 25% w/v solution in distilled water	LD_{50} = 1290 mg/kg bw	No toxic signs; no gross or microscopic lesions. CAUTION POISON	2300104
Dermal Toxicity	Rabbit 33% water solution administered to intact and abraded skin	LD_{50} = 580 mg/kg bw	WARNING POISON	2079417 2079418
Primary Eye Irritation	Rabbits 100 mg dry powder	Severely irritating (Average maximum score of 54/110 at 24 hours)	DANGER – EYE IRRITANT	2079417 2079418
Dermal Irritation	Rabbits 50 mg dry powder moistened with 0.1 mL of water to intact and abraded skin for an unspecified duration	Severely irritating (Primary irritation score : erythema 4/4; edema 4/4)	DANGER – SKIN IRRITANT	2079418
Dermal Sensitization Guinea Pig Maximization Test Mouse Ear Swelling Test	Guinea pig Mice	Negative	Not sensitizing	2079418

Table 2 Alternative Insecticides Registered for Use Against German Cockroaches Inside and Outside Buildings

Insecticide Group	Active Ingredients
Unclassified	Boron, D-limonene, German cockroach extract, Liquid carbon dioxide, Silicon dioxide
1A	Bendiocarb, Propoxur
1B	Chlorpyrifos, Dichlorvos, Malathion, Propetamphos
3A	Allethrin, Cyfluthrin, D-phenothrin, Imiprothrin, Lambda-cyhalothrin, Permethrin, Pyrethrins, Resmethrin, Tetramethrin
4A	Imidacloprid
6	Abamectin
7	S-methoprene
20A	Hydramethylnon

Table 3 Proposed and Accepted Use Claims

Claims proposed by applicant	Acceptable claims
PEST: Control of German cockroaches	**PEST:** Kills German cockroach nymphs and adults on contact
SITES: in and around buildings	**SITES:** as proposed.
DIRECTIONS FOR USE: MTDX-CR can be used in and around buildings to control accessible, exposed stages of German cockroaches. **Dilution:** Mix 10 g of product into 1 L of warm water. **Application Sites:** areas where these insects are usually found, such as cracks and crevices, niches, dark corners, drains and other harborage sites.	**DIRECTIONS FOR USE:** MTDX-CR can be used in and around building to kill German cockroach nymphs and adults. German cockroaches must be saturated with the spray solution. **Dilution:** as proposed. **Application Sites:** as proposed.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
2079406	2011, TGAI Chemistry Requirements, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7, 2.8,2.9 CBI
2079407	Production Procedure, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
2079408	2011, Preliminary Analysis, DACO: 2.12.1,2.13.2,2.13.3
2079409	2011, Preliminary Analysis Confidential Attachment, DACO: 2.12.1,2.13.2,2.13.3 CBI
2079410	2006, Stepan Company Analytical Method, DACO: 2.13.1 CBI
2079411	2011, Physical and Chemical Characteristics: Color, Physical State, Odor, pH, Melting Point, Bulk Density, and Water and Solvent Solubility, DACO: 2.14.1,2.14.2,2.14.3,2.14.4,2.14.6,2.14.7,2.14.8 CBI
2079412	2011, Chem and Phys Properties, DACO: 2.14.10,2.14.11,2.14.12,2.14.13,2.14.5 CBI
2079414	2011, Stepanol DX (AS 165) N Vapour Pressure, DACO: 2.14.9 CBI
2079415	2011, Accelerated Storage Stability Study, DACO: 2.14.14 CBI
2162159	2012, Starting Material Information, DACO: 2.11.2 CBI
2162160	2012, Catalyst information, DACO: 2.11.3 CBI
2162161	2012, Product Safety Laboratories Response, DACO: 2.13.1,2.13.2 CBI
2162162	Literature Serach for Dissociation Constant, DACO: 2.14.10 CBI
2195231	DX (AS165) Storage corrosion 052512, DACO: 2.14.14 CBI
2195235	Accelerated Storage Stability Data (Stepanol DX), DACO: 2.14.14 CBI
2076648	Table 2 - Chemistry Requirements for End Product – [Privacy Removed] - CR, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.2,3.4,3.5 CBI
2261046	Electro-oxidation of soidium lauryl sulfate aqueous solutions, DACO: 3.5.8

2.0 Human and Animal Health

2079421	1992, Sodium Lauryl Sulfate, DACO: 9.1
2079417	2007, NICNAS Existing Chemicals Information Sheet, DACO: 4.2.1, 4.2.2, 4.2.4, 4.2.5, 4.2.6, 4.3.1, 4.5.4, 4.5.5
2079418	2005, CHEMINFO, DACO: 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.5.4, 4.5.5
2079416	2009, Mammalian Toxicology of Sodium Lauryl Sulfate, DACO: 4.2.1, 4.2.2, 4.2.4, 4.2.5, 4.2.6, 4.3.1, 4.5.2
2185982	1993, EPA RED FACTS - Lauryl Sulfate Salts EPA-738-F-93-009
2076650	Ecolab Contact Formula - CR - Table 4 Occupational Exposure Information Requirements, DACO: 5.2
2076654	Waiver rationale for sodium lauryl sulfate, DACO: 6.1, 7.1

3.0 Environment

2079419 Technical Information: Stepan. Ecotoxicology of Sodium Lauryl Sulfate, DACO: 9.1

2079421 Sodium Lauryl Sulfate: Toxnet, Toxicology Data Network, DACO: 9.1

4.0 Value

2076653 2011, Average GCR Mortality at 24 Hours, Wet Forced Exposure - Table, DACO: 10.2

2185979 2012, 2011-2841 Response Cover Letter, DACO: 0.8

2185980 2012, Mode of Action Detail, DACO: 0.8

2185982 1993, EPA RED FACTS - Lauryl Sulfate Salts EPA-738-F-93-009, DACO: 10.6

B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

2300089 2009, EPA, Sodium Lauryl Sulfate; Exemption From the Requirement of a Tolerance, Federal Register /Vol. 74, No. 154 /Wednesday, August 12, 2009 /Rules and Regulations, DACO: 4.2.9

2300104 1983, Final Report on the Safety Assessment of Sodium Lauryl Sulfate and Ammonium Lauryl Sulfate, Journal of the American College of Toxicology, Volume 2, Number 7, DACO: 4.2.9

2.0 Environment

2287995 2000, IUCLID Dataset report, Substance ID:151-21-3 (Sodium dodecyl sulphate), DACO: 8.6, 9.9